

510(k) SUMMARY
Lanx Anterior Cervical Plate System

Submitter Information

Lanx, Inc.

APR - 7 2009

390 Interlocken Crescent, Suite 890

Broomfield, CO 80021

Contact Person: Andrew Lamborne

Date Prepared: February 6, 2009

Device Identification

Proprietary Name: Lanx Anterior Cervical Plate System

Common Name: Anterior Cervical Plate System

Classification: Spinal intervertebral body fixation orthosis, 21 CFR 888.3060

Predicate Device Information

Lanx Anterior Cervical Plate System

Intended Use / Indications for Use

The Lanx Anterior Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The Lanx Anterior Cervical Plate System is suitable for use to provide temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disc disease (neck or radicular pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion between and including levels C2 and C7.

Warning: This device is not cleared for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Technological Characteristics

The Lanx Anterior Cervical Plate System consists of anterior plates and bone screws that are used to build a construct to provide stabilization of the anterior cervical spine to support fusion. The system contains plates and screws of various sizes that allow the surgeon to address single or multi-level cervical spine conditions. The material for components of the Lanx Anterior Cervical Plate System is implant grade titanium alloy (Ti-6Al-4V ELI).

Performance Data

Performance testing was conducted to characterize the modified system. The Lanx Anterior Cervical Plate met the acceptance criteria and functioned as intended.

Substantial Equivalence

The Lanx Anterior Cervical Plate System is as safe and effective as the predicate device. The Lanx Anterior Cervical Plate System has the same or similar intended use, indications, technological characteristics and principles of operation as the predicate device. The minor differences between the Lanx Anterior Cervical Plate System and its predicate device do not raise new issues of safety or effectiveness. Mechanical testing also demonstrated comparable mechanical properties to previously cleared devices. Thus, the Lanx Anterior Cervical Plate System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Lanx, Inc.
% Mr. Andrew Lamborne
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

APR - 7 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K090316

Trade/Device Name: Lanx Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 9, 2009
Received: March 10, 2009

Dear Mr. Lamborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

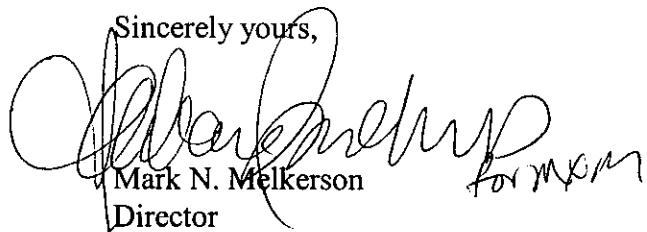
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090316

Device Name: Lanx Anterior Cervical Plate System

Indications for Use:

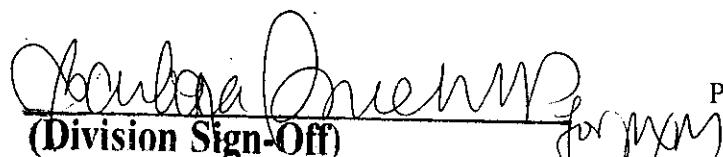
The Lanx Anterior Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The Lanx Anterior Cervical Plate System is suitable for use to provide temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disc disease (neck or radicular pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion between and including levels C2 and C7.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off) Page ____ of ____

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K090316